codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FH 05/37/4 – Add.1**
February 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-Seventh Session
Buenos Aires, Argentina, March 14 –– 19, 2005

COMMENTS ON THE PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

SUBMITTED BY

Australia, Mexico, New Zealand, Switzerland, the United States of America, Consumers International (CI), International Dairy Federation (IDF), International Dietary Foods Industry (ISDI)

GENERAL COMMENTS

AUSTRALIA

Australia supports the general content of the draft Code and its fast advancement. There are four specific points where Australia considers that further review is necessary.

NEW ZEALAND

The current draft revision (2004) of the Code is a much-improved document that addresses a number, but not all, of the issues raised by various international and national bodies. We believe, however, that there are still substantive issues that need to be clarified.

The document should be written with a long-term view rather than having undue emphasis on a controversial current issue (i.e., *E. sakazakii*). A more balanced approach should be taken with greater consideration given to other microorganisms of concern.

Throughout the document *infants at greatest risk* should be used as this term has been defined, rather than using the term *at-risk infants*. We suggest that the term should not be followed by text that then describes only a *sub-group* of the infants at greatest risk, unless this is intentional.

SWITZERLAND

Switzerland fully supports the revision of the Code of hygienic practice for foods for infants and children.

UNITED STATES OF AMERICA

The delegation from Canada and its drafting partners are to be congratulated on the significant progress that they achieved during the past year in the development of the *PROPOSED DRAFT RECOMMENDED*

INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR POWDERED INFANT FORMULA. The efforts of the working group have resulted in a significantly improved Code of Practice that incorporates the important concepts needed to assure the safety of powdered infant formula.

The Delegation of the United States feels that despite this excellent progress there are still several issues that need further discussion and debate. The United States has provided below specific points that the Committee may wish to consider to further strengthen the document.

CONSUMERS INTERNATIONAL

Consumers International commends the Working Group for its work on this important Code of Practice. We would like to offer the following comments.

Consumers International notes that the situation with powdered infant formula is a highly unusual one, in that intrinsic contamination of product meeting existing standards has been a cause of infection and illness in infants, including severe disease which can lead to serious developmental sequelae and death (as noted in the FAO/WHO Meeting Report on E. sakazakii and other microorganisms in powdered infant formula). CI believes that care must be taken in this Code to avoid giving any impression that the presence of a pathogen in a commercial product that kills infants is acceptable, even if it is currently not possible to eliminate the risk. Indeed, every effort must be taken to find ways to eliminate such contamination, and information provided to caregivers so as to allow them to assess the information and the choices available to them.

IDF

We recommend that the Code be written with a long-term view rather than having almost all emphasis on the controversial current issue (i.e. *E. sakazakii*).

Throughout the document, *infants at greatest risk* should be used as this term has been defined, rather than using the term *at-risk infants*. The term should not be followed by text that then describes only a *sub-group* of the infants at greatest risk, unless this is intentional.

TITLE

AUSTRALIA

The terminology "Powdered Infant Formula" is used in the title and through the document to cover several different types of products falling within its scope namely:

- infant formula
- follow-up formula
- formula for special medial purposes intended for infants
- human milk fortifiers
- above-mentioned products when used as ingredients in other infant foods (e.g. infant cereal products).

This is totally confusing given the specific definition in Codex of "infant formula" which does not cover all the abovementioned products.

Indeed, according to Codex, Infant Formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants **during the first months of life** up to the introduction of appropriate complementary feeding, whereas, Follow-up formula means a food intended for use as a liquid part of the weaning diet for the infant **from the 6th month on and for young children** (up to three years).

This confusion may also lead to a misinterpretation of the microbiological specifications defined in Annex I. The criteria provided in Annex I are appropriate to cover products intended for infants at particular risk

where *Enterobacter sakazakii* is a major concern. However, these specifications may not be entirely appropriate for some other products, e.g. follow up formula, for which *Salmonella*, and not *Enterobacter sakazakii,* is the major microbiological concern.

In order to solve this issue, Australia considers that there are two alternatives:

Alternative A

The Code should cover only infant formula, formula for special medical purposes intended for infants and human milk fortifiers.Then,Keep the title as is.

Modify Section II.1 Scope by deleting "follow-up formula" and the last sentence, see below.

*This Code covers products in powdered form specifically manufactured to be used for infants either as a breast milk substitute, to modify prepared breast milk substitutes or fortify human milk. Products included are infant formula, **~~follow-up formula~~**, formula for special medical purposes intended for infants and human milk fortifiers. **~~This Code also covers the above-mentioned products when used as ingredients in other infant foods (e.g. powdered infant formula as an ingredient of cereal-based foods for infants)~~***

Modify Section II.3 Definitions by deleting the paragraph on "Follow-up formula".

The rest of the document is acceptable, including Annex I the table with microbiological specifications, where all square brackets [ ] should be deleted.

Hygiene recommendations for follow-up formula - like other foods for infants and children - would be covered by the *General Principles of Food Hygiene* and other existing Codes of Hygienic Practices.

Alternative B

The Code should cover all products included in the present scope.

Then, the title should be changed and the words "powdered infant formula" should be replaced throughout the document.

Annex I Microbiological specifications should apply only to:

- Infant formula
- Formula for special medical purposes intended for infants, and
- Human milk fortifiers

All square brackets should be deleted.

A new table with microbiological specifications without criteria for *E. sakazakii* should be developed for Follow-up formula as well as for such formula powders used as ingredients in other infant foods (e.g. powdered infant formula as an ingredient of cereal-based foods for infants). **Australia's preference is Alternative A.**

SWITZERLAND

The Title of the Code has been amended to read "Proposed Draft Recommended International Code of Hygienic Practice for Powdered Infant Formula" instead of the current "Recommended International Code of Hygienic Practice for Foods for Infants and Children".

Switzerland fully understands the rationale behind this amendment; however, we believe that the term "Powdered Infant Formula" could be confusing. This term is not only used in the Title but also through out the document to designate different types of products (Infant formula, follow-up formula, formula for special medical purposes intended for infants, human milk fortifiers and above-mentioned products when used as ingredients in other infant foods (e.g. Infant cereal products). In our view, the Scope of the Code should be amended so that it reflects the specific Codex definition for "Infant Formula" (see below) which

does not cover all of the products listed in the Scope of the Draft Code.

Infant formula means a breast-milk substitute specifically manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding." Whilst,

Follow-up formula means a food intended for use as a liquid par of the weaning diet for the infant from the 6^{th} months on and for young children (up to three years).

In our view, it is appropriate to make a distinction between infant formula as defined above and other foods for infants since this distinction is crucial to the establishment of the appropriate and corresponding microbiological specifications defined in Annex I.

Switzerland can support the new Title provided that the necessary amendments are made in the Scope.

INTRODUCTION

GENERAL COMMENTS

NEW ZEALAND

The introduction focuses on *E. sakazakii*, with two paragraphs specific to this pathogen. This should either be minimised or removed, or some similar background material for *Salmonella* should be added.

No mention has been made of the potential contribution of biofilms of *E. sakazakii* formed in enteral tubes. Biofilms are likely to be a significant contribution to pathogen numbers in the infant gut and should be noted when considering risk reduction strategies.

IDF

The introduction focuses on *E. sakazakii*, with two paragraphs specific to this pathogen. This should either be minimised or removed, or some similar background material for *Salmonella* should be added.

No mention has been made of the potential contribution of biofilms of *E. sakazakii* formed in enteral tubes. Biofilms are likely to be a significant contribution to pathogen numbers in the infant gut and should be noted when considering risk reduction strategies.

Paragraph 2

NEW ZEALAND

Sentence 2, "Most reported cases have involved infants, however, reports have also described infections in children and immunocompromised adults."

This sentence should either be deleted or modified to clarify that E sakazakkii cases involving children and adults have been as a result of nocosomial infections

Rationale: The emphasis of this Code is "particularly for infant formula". Nocosomial *E. sakazakii* infections reported in adults and children are of no relevance to infant formula or for that matter, any other food. This sentence, as currently written, is therefore potentially misleading.

CONSUMERS INTERNATIONAL

Specifically, we recommend that on page 3, in the Introduction, the last sentence of the second paragraph be revised. Currently, it reads, "Clearly, developing and adhering to appropriate risk-reduction strategies are warranted."

This is a rather bland understatement. In our view it should read; "Clearly, every effort must be taken to (1) develop and implement strategies to minimize the risk, with the goal being to eliminate the risk, and (2) provide information to caregivers that allows them to make informed choices regarding the optimal care of the infant."

IDF

The emphasis of this Code is particularly for infant formula. Nosocomial E. sakazakii infections reported in adults are of little relevance to infant formula and thus for this Code. Consequently, this sentence is redundant and could be deleted

Paragraph 3

NEW ZEALAND

Sentence 1 – clarification "The group at particular risk <u>from E. sakazakii infection</u> is infants ...."

Rationale: This definition is from the WHO risk assessment and applies to *E. sakazakii*.

Additional paragraph to Introduction

Infants, depending on their age and health, consume a range of milk formula products. The microbiological criteria for the different products should therefore reflect the risk status of these different infant sub-groups**.**

Rationale: The Codex Principles for the Establishment and Application of the Microbiological Criteria for Foods (CAC/GL 21-1997) makes it clear that "A microbiological criterion should be applied only when there is a definite need" - - - (and where there is) "evidence of actual or potential hazards to health". On this basis, there is a need to make realistic groupings of infants on the basis of established/potential risk, and to ensure that the appropriate microbiological criteria are applied to formula targeted at each of these groups.

Additional paragraph to Introduction

A combination of strategies can reduce the risks that the consumption of recombined powdered infant formula present to infants. The single greatest reduction in risk can be achieved by careful handling of recombined formula to minimise the opportunity for growth of pathogenic organisms. While manufacturing controls, labelling and education are extremely important, the WHO risk assessment for E. sakazakii has shown that careful handling has a significantly greater impact on risk reduction.

Rationale: The potential for growth of *E. sakazakii* in the reconstituted formula has been modelled in the WHO risk assessment. The modelling demonstrated that if the contamination rate in the powder increases from 0.0001 to 0.025 then the risk factor only increases 4.9 fold. However, if the reconstituted formula holding time is increased from 4 to 8 hours then there is a 1000 fold increase in the risk factor. Therefore, the greatest impact on risk reduction can be achieved through careful handling of the reconstituted formula. It is essential that the importance of careful handling of the reconstituted formula be emphasised in the introduction and throughout this document.

IDF

Para. 3, 3rd sentence

The statement of the first sentence applies to *E. sakazakii*. This should be made clear, e.g. by rewording the sentence into:

"The group at particular risk <u>from E. sakazakii infection</u> is infants ...."

Additional para. To Introduction

The potential for growth of *E. sakazakii* in the reconstituted formula has been modelled by WHO (see report of the Joint FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula, 2–5 February 2004). The modelling demonstrated that if the contamination rate in the powder increases from 0.0001 to 0.025 then the relative risk only increases 4.9 fold, whereas changing holding time in the reconstituted formula from 4 to 8 hours the relative risk increase 1000 fold.

The modelling also indicated the impact of pos-manufacture reduction (e.g. planned storage) have a high impact (e.g. 4-log reduction reduce relative risk 10,000 fold). Therefore the greatest impact on risk reduction can be achieved post-manufacturing, including through careful handling of the reconstituted formula.

We find this information important to be highlighted in the introduction and suggest the inclusion of the following paragraph:

"A combination of strategies can reduce the risks of E.sakazakii infection related to the consumption of recombined powdered infant formula by infants. By far the single greatest reduction in risk can be achieved by careful handling of recombined formula to minimize the opportunity for growth of pathogenic organisms. Consequently, adequate labelling and education is an important control measure."

ISDI

First sentence; replace "(i.e. children < 1 year)" by "infant below 6 months of age".

Rational: As recognized in the FAO/WHO expert report on E. sakazakii and other microorganisms in powdered infant formula[1], premature and immunocompromised infants are considered to be particularly at risk of E. sakazakii infection than term infants. Additionally, the European Food Safety Authority in their "Opinion of the Scientific Panel on Microbiological Hazards on the request from the Commission related to the microbiological risks in infant formulae and follow on formulae (EU terminology for follow-up formulas)[2]" recently noted "the widespread distribution of E. sakazakii suggests that consumption of low numbers in infant formula and follow-on formula by healthy infants and children does not lead to illness"

For these reasons, the first sentence of this paragraph is too broad as all infants below 1 year are not considered at risk

II.1 SCOPE

SWITZERLAND

Given the specific concerns which led to the revision of the Code, and bearing in mind the discussions which took place at the Working Meeting, as well as the comments given above under Title, Switzerland would like to propose that the Scope be amended so that the Code only covers the following powdered products:

- Infant formula
- Formula for special medical purposes intended for infants
- Human milk fortifiers

Consequently, follow-up formula and above-mentioned products when used as ingredients in other infant foods (e.g. powdered infant formula as an ingredient of cereal-base foods for infants) should be deleted from the Scope.

Proposed amendment to the Scope:

"This Code covers products in powdered form specifically manufactured to be used for infants either as a breast milk substitute, to modify prepared breast milk substitutes or fortify human milk. Products included are infant formula, ~~**follow-up formula**~~, formula for special medical purposes intended for infants and human milk fortifiers. ~~**This Code also covers the above-mentioned products when used ingredients in other infant foods (e.g. powdered infant formula as an ingredient of cereal-based foods for infants).**~~

[1] http://www.fao.org/es/esn/food/risk_mra_riskassessment_entero_en.stm
[2] http://www.efsa.eu.int/science/biohaz/biohaz_opinions/691/biohaz_opinion14_ej113_microrisks_v2_en1.pdf

ISDI

First sentence, follow-up formula"

Rational: Follow-up formulas are not infant formulas. They are defined in the Codex Standard for Follow-up Formulas, Codex STAN 156-1987 (amended 1989), they are not breast milk substitutes and they are intended for older infants from 6 to 12 months of age.

The title of the Code clearly shows that the Code is intended for powder infant formula.

Finally, follow up formulas constitute the liquid part of a progressively diversified diet.

As clearly stated in the Background section of the Codex document, *the Code covers exclusively powdered products used for infants*, while *hygiene recommendations for foods for infants and children other than powdered infant formula* (thus including follow-up formula), *covered by the previous document, are considered to be appropriately covered by the General Principles of Food Hygiene and other existing Codes of Hygienic Practices*.

Finally, follow-up formula does not represent the same risk as infant formulas. As stated in the EFSA report, p. 14 under section *3.1 Epidemiology and pathogenicity*, "*It should be emphasised that no incidents similar to those above* (in infant formula) *have been associated with follow-on formulae*."

II. 3 DEFINITIONS

NEW ZEALAND

We believe that it would be helpful for the text of the referenced definitions to be included in this document.

Infants at greatest risk

NEW ZEALAND

Clarification of the "***Infants at greatest risk"*** definition. This definition is from the WHO risk assessment and relates to *E. sakazakii*. We consider that care needs to be taken when transposing this across all microorganisms of concern in infant formula.

IDF

It is questioned whether this definition relates only to *E. sakazakii*. Whether this same group is also the group at greatest risk in regard of other hazards (other pathogens, and chemical and physical hazards) should be clarified.

Follow-up formula

SWITZERLAND

In light of our comments above, we propose that the definition for "Follow-up formula" be deleted.

~~**Follow-up formula - as defined in the Codex Standard for Follow-up formula, Codex STAN 156-1987 (amended 1989)**~~

IDF

The definition stated in CODEX STAN 156 should be shown in a note, as it is important to highlight the fact that these products are targeted to infants who are not in the greatest risk category, i.e. add:

"Note: A food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children."

Wet-mix, Dry-mix and Combined process

NEW ZEALAND

Add the word manufacturing at the start of each definition sentence. "*manufacturing process by which ....*" to distinguish from reconstitution procedures.

IDF

The word manufacturing should be added at the start of each definition sentence ie "*manufacturing process by which ....*" to distinguish these products from reconstitution processes/procedures.

Dry-mix process

MEXICO

According to the term used, it would appear that it deals exclusively with the process of mixing dry ingredients. However, the definition refers to two separate operations, one consisting of the application of treatments to dehydrate the ingredients, and the other one of the mixing of dry ingredients, which is inconsistent with the term to be defined. Therefore, we ask that it be clarified.

This issue has an impact on numeral V.2.2 Specific process steps, particularly concerning "Blending", and on numeral V.3 Incoming material requirements.

SECTION V. - CONTROL OF OPERATION

NEW ZEALAND

General Comment

In order to ensure consistency it is important that this Code follow the established Codex framework. We suggest that the current text could be replaced with a reference to section 5 of the recently adopted Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004). For example:

"Microorganisms present in raw milk should be controlled in accordance with section 5 of the Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)."

Rationale: Raw milk always contains microorganisms and, according to the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004), any harmful organisms present must be controlled by a combination of control measures that ensures that acceptable levels (FSOs and related criteria) are met. Such combination includes microbiostatic control measures and, where necessary, microbiocidal measures.

SECTION V.1 CONTROL OF FOOD HAZARDS

1st Paragraph

AUSTRALIA

Modify Section V.1 Control of Food Hazards by inserting the words "GHP (Good Hygienic

Practices) and" in the first sentence after "use of" to read:

"Manufacturers should control food safety hazards through the use of a food safety management system based on HACCP (or the HACCP approach) refer to the Annex Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application of the General principles of Food Hygiene. This allows flexibility for the 'system' to include GHP/HACCP or however it is expressed in by different national legislation or guidelines/standards."

SWITZERLAND

We would like to propose the addition of Good Hygienic Practices (GHP) since these are also recognised as food safety control measures.

Therefore the amended sentence would read as follows: "Manufacturers should control food safety hazards through the use of Good Hygienic Practices (GHP) and a HACCP system ..."

UNITED STATES OF AMERICA

The U.S. Delegation recommends that this paragraph be modified to better emphasize the importance of good hygienic practices. Also, insert the word "Point" after "Control" in the parenthetical.

Manufacturers should control food safety hazards through the use of **GHP (Good Hygienic Practices) and** a HACCP system (refer to the Annex *Hazard Analysis and Critical Control* ***Point*** *(HACCP) System and Guidelines for its Application* of the *General Principles of Food Hygiene*. A system based on expert advice and involving documentation would be appropriate. In particular, manufacturers should:

Section V.2.1 Time and temperature control

Paragraph 1

NEW ZEALAND

Amend first paragraph.

"Temperature recording devices (for both heating and chilling control points) should be checked at regular intervals…"

Rationale: To provide clarification regarding the scope of the paragraph

Paragraph 3

NEW ZEALAND

Replace sentence*"For raw milk and other foods..."* with: *Temperature control should be considered thoroughly at both heating and chilling control points*. And move this sentence to the beginning of the section.

Rationale: Clarification of the intent of this sentence.

Section V.2.2 Specific Process Steps

AUSTRALIA

Australia does not consider it appropriate for the Code to address Specific Process Steps in such detail. Manufacturing processes are continuously improving as new technologies become available. Consequently, the prescription of specific technologies is not advised as this may impede development of more optimal processes. We therefore suggest that this whole section is deleted or modified.

At the very least we do not consider it advisable for the Code to define detailed specifications for manufacturing equipment (i.e. High Efficiency Particulate Air filters (EU≥10) for air used for fluidised cooling beds) since there are other appropriate solutions depending upon the manufacturing technology.

IDF

We note that levels of *E. sakazakii* will be reduced in powdered product during storage (0.5 log reductions per month have been reported). Consequently, acceptable levels can occur later than immediately after manufacture. Therefore, planned storage time is an effective control measure that should be addressed as a possible specific step.

Thermal processing - Second bullet

MEXICO

For wet-mix process

We ask to have specified in the last paragraph that the reduction refers to vegetative microorganisms, particularly to pathogens.

Air chilling - Fourth bullet

AUSTRALIA

We suggest that the wording of the first sentence of the "Air chilling" section be modified to:

*During the drying process, the powder should pass from a drying chamber to a fluidised cooling bed where it is quickly cooled in an appropriate manner, for example, **~~using cool air filtered through High Efficiency Particulate Air (HEPA) filters (EU≥10)~~ with appropriately filtered cool air.***

SWITZERLAND

In our view, it does not seem appropriate for the Code to describe in such detail the drying process which could be used although we understand that the technique mentioned is given as an example. We would thus propose that the detailed specifications for manufacturing equipment be deleted, since there could be other appropriate solutions world-wide, depending on the manufacturing technology. We would therefore propose that the following amendment be made to the first sentence:

During the drying process, the powder should pass from a drying chamber to a fluidised cooling bed where it is quickly cooled in an appropriate manner**~~, for example, using cool air filtered through High Efficiency Particulate Air (HEPA) filters (EU ≥ 10).~~**

UNITED STATES OF AMERICA

The U.S. Delegation recommends that the paragraph on air chilling be modified to be less prescriptive:

During the drying process, the powder should pass from a drying chamber to a fluidized cooling bed where it is quickly cooled in an appropriate manner, for example, ~~using cool air filtered through High Efficiency Particulate Air (HEPA) filters (EU ≥ 10)~~ **with appropriately filtered cool air**. Air filters should be tightly fitted and properly sealed against gaskets to prevent the entrance of unfiltered air. Outside air intakes should be located away from the exhausts of the drier, boiler and other environmental contaminants. Filters should be changed or cleaned and sanitized regularly.

For wet-mix process:

Delete "~~for example, using cool air filtered through High Efficiency Particulate Air (HEPA) filters (EU > ≥10)~~"

Rational: the Code should not mention any specific type of filters as different technological options exist to obtain the same result described.

Thermal processing - for wet-mix process

IDF

The sub-title and the text of the first paragraph should be reviewed. Other microbiocidal control measures may achieve the same level of control and the first para. may read as if not all control measures used need to be effective.

Note: The term "Microbiocidal treatment" is defined by the Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) as a control measure that substantially reduce or practically eliminate the number of microorganisms in a food.

We suggest the following rewording (suggested changes highlighted):

"~~Thermal processing~~ Microbiocidal treatment

For wet-mix process:

If some raw ingredients are used, such as raw milk, and likely to be contaminated with pathogenic microorganisms, microbiocidal ~~effective~~ control measure(s) such as heat treatment that effectively control these hazard(s) is necessary"

Blending - <u>For dry mix and combined processes</u>

NEW ZEALAND

The text departs from the Codex Code of Hygienic Practice for Milk and Milk Products in mandating use of a thermal process in relation to dry ingredients. This should be modified to reflect the Code

CONSUMERS INTERNATIONAL

We recommend that the word "avoid" be replaced with the phrase "prevent or minimize." Since this stronger language is certainly warranted when dealing with a pathogen where infants are at risk of serious illness or death. Thus the sentence would read; "Blending should be done under strict hygienic conditions to PREVENT OR MINIMIZE {delete: avoid} contamination of the final product."

And similarly in this same section, under Packaging, it should read: "Upon completion of the drying and/or blending steps, the final product is filled into cans or flexible containers. This step needs to be done under strict hygienic conditions to PREVENT OR MINIMIZE contamination of the final product."

IDF

The text in the second sentence departs from the Codex Code of Hygienic Practice for Milk and Milk Products in mandating use of a thermal process in relation to dry ingredients. Other combinations of microbiocidal and microbiostatic control measures, applied during or after manufacture, may achieve the same level of protection.

Note: The term "Microbiostatic treatment" is defined by the Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) as a control measure that minimize or prevent the growth of microorganisms in a food.

We suggest the following rewording (suggested changes highlighted):

"*Dry ingredients used at this stage should<u>, during appropriate points during and/or after their manufacture,</u> have been subjected to <u>a combination of microbiocidal and microbiostatic control measures that effectively control microbial hazards relevant to infant formulae</u>* ~~*a thermal process (see above) at an appropriate point in the manufacture*~~."

V.2.3. Microbiological and Other Specifications

SECOND PARAGRPH

AUSTRALIA

Modify Section V.2.3: " Microbiological and other specifications, second paragraph by deleting "other *Enterobacteriaceae* ..." after "*Salmonella"*, so as to read: "*The main microbiological issues associated with powdered infant formula are related to the presence of Salmonella and* ~~***Enterobacteriaceae, including***~~ *E. sakazakii. In addition, manufacturers may consider...etc."*

UNITED STATES OF AMERICA

This document deals primarily with the control of *Salmonella* and *Enterobacter sakazakii* as the hazards of greatest concern. *Enterobacteriaceae* testing may have value as an indicator of hygienic manufacturing practices, but should not be listed in the same context as these two pathogens.

The U.S. Delegation recommends that the paragraph be modified to read:

The main microbiological issues associated with powdered infant formula are related to the presence of *Salmonella* and ~~other *Enterobacteriaceae*, including~~ *E. sakazakii*. In addition, manufacturers may consider testing for other appropriate microorganisms, as a means of assessing the hygienic conditions and practices employed in the manufacturing of the product. Microbiological specifications relevant to powdered infant formula are listed in Annex I.

ISDI

Reword the second paragraph to read:

"The main microbiological issues associated with powdered infant formula are related to the presence of *Salmonella* and other *Enterobacteriaceae*, including *E. sakazakii*. In addition, manufacturers may consider testing for other appropriate microorganisms.

~~Microbiological specifications relevant to powdered infant formula are listed in Annex I.~~

Specific microbiological criteria for powdered infant formulae for high-risk infants are provided in annex I. These criteria are used to demonstrate the acceptability of products and food lots by Public Health Authorities.

Rational: ISDI welcomes the differentiation made between:

- the microbiological criteria to be applied by controlling authorities on the end product, in the absence of knowledge of the process used by the manufacturer (as described in Annex I), and
- the verification procedures to be applied by manufacturers to ensure compliance of the commercialised products, which are defined by the manufacturer itself depending on its process (as recommended in Annex II).

Still, ISDI suggests alternative and additional wording in order to further clarify in this Code this concept.

THIRD PARAGRPH

CONSUMERS INTERNATIONAL

Consumers International agrees with the statement in V.2.3 at the bottom of p 6 that "Manufacturers are responsible to ensure compliance of finished products." But, no mention is made of government's role. We suggest that it read; "Manufacturers are responsible to ensure compliance of finished products. In addition, government authorities should conduct oversight and surveillance activities to further ensure compliance of finished products."

ISDI

Modify the paragraph to read; "Manufacturers are responsible to ensure compliance of finished products. In view of the limitations of end product testing, **manufacturers will ensure** compliance ~~should be ensured~~ through the design of an appropriate food safety control system **elements of which are outlined in section V**, verification of the effectiveness of control measures through appropriate auditing methods, including review of monitoring records and of deviations and confirmation that CCPs are kept under control. These activities should be supplemented, as necessary, by microbiological testing based on random sampling and analysis. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, production line, environment and finished products. ~~Verification procedures using environmental testing for powdered infant formula are described in Annex II~~. **Sampling and testing levels and frequencies need to be defined according to monitoring programs. Guidelines on the establishment of such programs are provided in annex II."**

LAST PARAGRPH

IDF

A "control measure" is defined very broadly and includes control measures applied in prerequisite programs (see Annex I to CX/FH 05/37/07). Deviations in the functioning of many control measures (e.g. cracks in building walls, non-compliance to food safety related labelling instructions) do not necessarily require a withholding of the product.

Consequently, the term "*control measures*" should be replaced by "*CCPs*", as a CCP is defined as an essential step, and if monitoring shows that a from critical limit has been exceeded, the product cannot be released until adequate verification has shown that it complies with the specifications.

V.3 INCOMING MATERIAL REQUIREMENTS

NEW ZEALAND

Is allergen control relevant to a hygiene document? Allergen control is generic to all food processing.

V.4 PACKAGING

CONSUMERS INTERNATIONAL

Similar to our previous comment, the sentence on P. 8, section 5.4, should be revised to read: "Packaging design and materials should provide adequate protection for products to PREVENT (WHERE POSSIBLE) OR minimize contamination, prevent damage, and accommodate proper labelling."

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENES

OBVECTIVES

CONSUMERS INTERNATIONAL

While overall the section on objectives in section IX is well written, an essential point is missing. No mention is made of providing caregivers with information about the risk, and its severity, which is precisely the reason why appropriate measures are so important. Knowing that there is a risk, albeit small, of serious illness or death is important information, and very different than, for example, the risk of dermal irritation. Knowing the severity of the risk is important to heighten awareness of the importance of following all handling instructions, which can in turn prevent serious illness and death. Thus, the last sentence of the objectives should be revised to read:

"Caregivers of infants in the home, day care and health-care facilities and health-care professionals should be informed that the product does not undergo a sterilization process AND THAT PRODUCT MAY BE INTRINISCALLY CONTAMINATED WITH PATHOGENS THAT ARE LIFE-THREATENING TO INFANTS, AND THEY should be provided with sufficient information on food hygiene to enable them to:"

RATIONALE

CONSUMERS INTERNATIONAL

Similarly, on page 9, the statement under RATIONALE should be revised to read

"Insufficient product information, and/or inadequate knowledge of general food hygiene, OR THE RISKS INVOLVED, INCLUDING THEIR SEVERITY, can lead to powdered infant formula being mishandled at later stages in the food chain. Such mishandling can result in illness, even when adequate hygiene control measures have been taken earlier in the food chain."

IX. 3. LABELING

NEW ZEALAND

Agree with the labelling provisions particularly with respect to the absence of a sterilisation process.

UNITED STATES OF AMERICA

The U.S. Delegation continues to be concerned that recommendations for warning labeling be carefully considered. The current draft states that "Labels should be considered on products, reminding those who prepare formula and who feed infants that powdered infant formulas do not undergo a sterilization process." We are concerned that this not be interpreted as a need for a warning statement on powdered infant formula, but should be used as a part of a larger care-giver and health professional educational

program. The use of cautionary or warning labeling on powdered infant formulas in the absence of effective care-giver and health professional education could cause confusion or inappropriate action. In many areas of the world, there is no alternative other than breast milk to the use of powdered infant formula. When there is no sterile alternative product, consumers may be motivated to use other products, such as powdered milk, that does not have cautionary labeling but is entirely inappropriate for infant feeding. Information on the risks of powdered infant formula and appropriate alternatives (if powdered formula alternatives are available) or handling methods can be effectively communicated by means other than a product label. This is particularly true since product labels are already crowded with important information and consumers may not always read all of the information on product labels. For example, education of consumers by health care professionals may be an effective alternative to cautionary product labeling.

The U.S. Delegation recommends that the paragraph on labeling be reworded as follows:

~~Labels~~ **Information (or Language)** should be considered ~~on products~~, reminding those who prepare formula and who feed infants that powdered infant formulas do not undergo a sterilization process. Therefore, the label should contain appropriate information regarding the need for proper preparation, handling and storage of reconstituted powdered infant formula to prevent or minimize bacterial growth.

CONSUMERS INTERNATIONAL

In Section IX.3 on labeling, it is not sufficient to only label the product with information that it is not sterile. The process the product undergoes is not the important point; the point is that there is a risk that the "product" even unopened product right off the "shelf" may contain pathogens capable of causing very serious illness or death to infants. This section as currently drafted does not provide any information to the caregiver about the risk and the importance of risk-reduction strategies. Also, it is not sufficient to only consider adequate labels; there should in fact be adequate labeling. Consumers International believes it is important that there be a clear and forthright statement. It should be revised, in our view, as follows: Labels should be INCLUDED {delete: considered} on products, WITH INFORMATION INTENDED FOR (delete: reminding} those who prepare formula and who feed infants, that powdered infant formulas do not undergo a sterilization process AND MAY CONTAIN PATHOGENS THAT CAN CAUSE SERIOUS ILLNESS OR DEATH TO INFANTS. Therefore, the label should contain appropriate information regarding {delete: the need for} proper preparation, handling and storage of reconstituted powdered infant formula to prevent or minimize bacterial growth.

ISDI

Reword the first sentence to read "to read "**~~Labels~~ Information should be considered ~~on products~~ ",** reminding those…"**,** and move to section IX.4 Education.

Rational: The word "labels" should be changed into "information in order not to suggest that mandatory labelling is required. The content of this paragraph belongs more in the Section "Education" than to section "Labelling".

IX.4 EDUCATION

SECOND PARAGRAPH

MEXICO

We ask that the second paragraph and the first bulleted point of the fifth paragraph be fused together to avoid repetition.

CONSUMERS INTERNATIONAL

In section IX.4, we recommend the draft be revised to include information on how the caregiver can influence the risk. Also, the term "intrinsic contamination" was the term used in the FAO/WHO meeting report on E. sakazakii and other microorganisms in powdered infant formula, and is preferable to less

precise and more subjective characterizations such as "extremely low." The current draft uses different adjectives (e.g., "low" in the introduction and "extremely low" in this section) when discussing levels of pathogens in powdered infant formula. Thus we suggest that the second paragraph in this section be revised to say: Caregivers of infants in the home, day care and health-care facilities and health-care professionals involved in caring for infants should be aware that powdered infant formula is not a sterile product and may be INTRINSICALLY contaminated, on occasion, with {DELETE: extremely low levels of} pathogens that can cause serious illness OR DEATH. THE RISK OF SERIOUS ILLNESS OR DEATH CAN BE INCREASED in case of mishandling or improper storage of reconstituted infant formula.

And similarly that the first bulleted statement in this section be revised to say: They should be informed that powdered infant formula may be INTRINSICALY contaminated with {delete: extremely low levels of} pathogens that can cause rare but serious illnesses OR DEATH, particularly for infants at greatest risk.

At the end of section IX.4, we suggest that the following bullet be added: Promptly discarding unused feeds immediately after feeding.

And, that the last bullet of the section be revised as follows: Keeping a daily record of WHICH INFANTS RECEIVED WHICH product and lot number.

Finally, it should be noted in Section IX.4 that educational programs should conform with the World Health Organization Code of Marketing of Breast-milk Substitutes adopted at the 34th World Health Assembly (WHA34.22, 1981).

ISDI

First sentence, Reword "*do not undergo a terminal sterilization process*" instead of "*is not sterile*"

Rational: infant formula, like any other food is not supposed to be sterile, the proposed wording is in line with the beginning of the section on Labeling.

FOURTH PARAGRAPH

NEW ZEALAND

Rewording of 4th paragraph

"It should be noted that the addition of other ingredients to infant formula (whether in powder or liquid form) may also present the potential for contamination which will require stringent preparation and storage conditions equivalent to those for unadulterated, commercially manufactured infant formula."

Rationale: All infant formulae, whether they contain added ingredients or not, need to be treated with the same care.

IDF

All infant formulae, whether they contain added ingredients or not, need to be treated with the same care. Consequently, the para. should be reworded as follows (suggested changes highlighted):

> *"It should be noted that the addition of other ingredients to infant formula (whether in powder or liquid form) may also present the potential for contamination which ~~may~~ will require ~~more~~ stringent preparation and storage conditions equivalent to those ~~than that~~ for, commercially manufactured infant formula."*

FIFTH PARAGRAPH

AUSTRALIA

In the 5th Paragraph, 3rd square dot point, 3rd sub-point square bracketed text, Australia considers that this should read [a maximum of 6 ° C fro 24 h, **or as required by national legislation**]

NEW ZEALAND

Addition of a bullet point under the fifth paragraph;

When travelling (or away from home) the caregiver should be advised on the best means of preparing infant formula (e.g., the use of pre-measured portions of powder, which are able to be mixed with pre boiled water).

Rewording of the bullet points under the fifth paragraph

Remove the first bullet point and incorporate it into the last. Suggest rewriting the bullet points as follows

- When feasible, commercially available sterilized liquid products should be used to feed infants at greatest risk, rather than powdered infant formula.
- When using and handling powdered infant formula, the following should be emphasized to minimize risk:
  - Powdered infant formula is not a sterile product. Therefore, if the reconstituted product is mishandled there is a risk that pathogenic contaminants may grow to levels that will cause rare, but serious illnesses, particularly in infants at greatest risk.
  - Strictly adhere to manufacturer's instructions.
  - Reconstituted formula should not be kept in the refrigerator (< 6C) for any longer than 24 hours and ideally shorter times are better
  - Reconstitute only the amount needed for the infants next feed and that this occurs as close as possible to feeding time
  - Leftovers of reconstituted infant formula should be discarded.

Rationale
The first bullet point in the document which addresses contamination of powdered infant formula with pathogens is difficult to convey to caregivers and should really be part of the third bullet point that covers use and handling of infant formula.

Within the third bullet point, the third point ("*Minimise the length of time between reconstitution ...*") has too little detail to be helpful to caregivers.

IDF

The first bullet point which addresses contamination of powdered infant formula with pathogens is difficult to convey to caregivers and should really be part of the third bullet point that covers use and handling of infant formula. Within the third bullet point, the third point ("Minimise the length of time between reconstitution ...") has too little detail to be helpful to caregivers.

With regard to the square bracketed temperature/time specification, we would like to draw the attention to the CCFH of the fact that growth of all strains of E. sakazakii occurs at 6 °C (see Iversen, Lane & Forsythe The growth profile, thermotolerance and biofilm formation of Enterobacter sakazakii grown in infant formula milk. Letters in Applied Microbiology 38:378-382 (2004), as well as the report of the FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula, February 2004). A storage temperature of 4 °C would be more appropriate.

The above recommendations are, together with suggestion for clarification of the text, shown in the recommended rewording below (suggested changes highlighted):

- ~~**They should be informed that powdered infant formula may be contaminated with extremely low levels of pathogens that can cause rare but serious illnesses, particularly for infants at greatest risk.**~~
- *When feasible, ~~the use of~~ commercially available sterilized liquid products should be used ~~as a replacement for powdered infant formula when feeding~~ to feed infants at greatest risk, ~~particularly neonates of low birth weight (<2 500 g)~~, rather than powdered infant formula.*
- *When using and handling powdered infant formula, the following should be emphasized to minimize risk:*
  - *Powdered infant formula is not a sterile product. Therefore, if the reconstituted product is mishandled there is a risk that pathogens may grow to levels that will cause illness*
  - *Strictly adhere to manufacturer's instructions.*
  - *Reconstitute and feed immediately, particularly when adequate refrigeration is not available;*
  - ~~*Minimize the length of time between reconstitution and consumption of powdered infant formula. Attention should be paid to the length of time that formula is: i) kept at room temperature ii) stored in the refrigerator [a maximum of 6 °C for 24 h], and iii) retained after feeding has begun3;*~~ *The temperature and time for storing reconstituted formula should not exceed ~~[6~~ **4** °C and 24 hours respectively~~]~~*
  - *Leftovers of reconstituted infant formula should be discarded.*

ISDI

◊ Delete first bullet point and modify the first diamond bullet point to read "Strictly adhere to manufacturer's instructions **(including handling of feeding material)."**

Rational: the idea addressed in this point is already addressed in the following ones. Contamination of the product may occur via contaminated feeding material.

For Health –care provider/professional and hospitals

FIRST SQAURE DOT POINT

NEW ZEALAND

Remove the text "*particularly neonates of low birth weight (<2 500 g)",* as this is already included in the definition of "infants at greatest risk"

After the sentence on the final decontamination procedure, it should be noted that such heat treatments may carry the risk that heat labile components of the infant formula will be destroyed.

UNITED STATES OF AMERICA

The U.S. Delegation believes that care-giver education is a very important component of the overall effort to control the risk of *E. sakazakii* infection. Point of use pasteurization may be effective for many formulas; however, some formulas are denatured or damaged by excessive heating. Thus, we recommend the following addition to the first bullet point under the section for health care providers/professionals and hospitals.

When feasible, the use of commercially available sterilized liquid products should be used as a replacement for powdered infant formula when feeding infants at greatest risk, particularly neonates of low-birth weight (<2500 g). Reconstituted formula which has undergone an effective final decontamination procedure could also be used in a hospital setting (e.g., use of a commercial steamer in formula preparation). **However, the preparer must follow appropriate guidance to ensure that the nutritional integrity and safety of the reconstituted formula is maintained.**

IDF

The text "*particularly neonates of low birth weight (<2 500 g)"* should be removed, as this is only a sub-group of the infants at greatest risk and is therefore misleading.

SECOND SQUARE DOT POINT

AUSTRALIA

In the second square dot point, 7th sub-point square bracketed text, Australia considers that this should also read [a maximum of 6 ° C fro 24 h, or as required by national legislation].

MEXICO

In the second to last bulleted point, it should be indicated that the storage consists of a maximum of 6 ºC for 24 hours.

ISDI

Last diamond point; add the same footnote as the section above to read "[a maximum of 6°C[3]]."

[3] Risk assessment modeling of time and temperature may provide guidance

Rational: the maximum temperature and time at which reconstituted product can be stored in hospital should also be determined by the risk assessment model (as for storage of reconstitutes formula at home or at day-cares)

ANNEX I: MICROBIOLOGICAL SPECIFICATIONS FOR POWDERED INFANT FORMULA

TITLE

ISDI

After "FORMULA" add "**FOR INFANTS BELOW 6 MONTHS"**

Rational: as clearly stated in the scope of the draft Recommended Code of Hygienic practice, "infants under 6 months of age are at particular risk. Among infants at particular risk, neonates (up to four weeks of age), pre-term infants, low-birth-weight or immunocompromised infants are particularly at risk.

In addition, in the latest version of the Draft revised Codex Standard on Infant Formula (Alinorm 05/28/26) infant formulae is defined as "*suitable for satisfying by itself the nutritional requirement of normal healthy infants during the first months of life" i.e. for infants below 6 months*.

First Paragraph

NEW ZEALAND

First paragraph – Modify

"It is important that microbiological specifications are established in the context of risk management options". A number of factors (known and unknown) will have an impact on the level of pathogenic micro-organisms found in reconstituted powdered infant formula. During manufacture, steps should be taken to minimise contamination, particularly in the post-drying section of the process

Rationale: The modification clarifies that the issue is not just about E. sakazakii or Salmonella

The potential for final product contamination is greatest in the post drying portion of manufacturing.

IDF

The 2nd and 3rd sentences do not belong here and are covered by the main body of the Code.

If, however, these sentences are retained, they should read (changes highlighted):

"A number of factors (known and unknown) will have an impact on the level of pathogenic microorganisms found in reconstituted powdered infant formula. Steps should be taken during manufacturing to minimize post-drying contamination ~~the likelihood that microorganisms of concern (e.g., Salmonella and E. sakazakii) will be present~~.

The changes suggested to the 2nd sentence clarifies that the issue is not just about *E. sakazakii* and *Salmonella*.

The changes suggested to the 3rd sentence are recommended, as the current wording implies that it is possible to selectively minimize the likelihood that certain specific undesirable microorganisms will be present. This is incorrect, as steps can only be taken to minimize the total level of post-drying contamination.

Microbiological Criteria Table

NEW ZEALAND

We propose that the table should include notes (either footnotes or an additional column) that define the age-group that each microbiological criterion applies to. For example it may be appropriate that E. sakazakii criteria apply only to products destined for infants < 6 months.

Rationale: There is no evidence that infants > 6 months are at significant risk from E. sakazakii when fed follow-up or toddler milk formula. Hence it may not be appropriate that these products have microbiological criteria set for E. sakazakii.

Table Footnote ** modify to

** Compliance with this criteria indicates control of process hygiene.

Rationale
The existing statement assumes a direct relationship between Enterobacteriaceae levels and E. sakazakii that has not been established. The proportions of E. sakazakii to Enterobacteriaceae will vary between and within manufacturing plants.

Enterobacteriaceae are good indicators of plant and process hygiene. Therefore, it is valid to use Enterobacteriaceae to reflect hygiene control, as discussed in Annex 2. However, the proposed Enterobacteriaceae limits are significantly more stringent than current Enterobacteriaceae levels (which are generally around the per g level). Is there sufficient data to support this significant change?

The annex seems to imply that:

- A safe Enterobacteriaceae / E. sakazakii ratio can be determined. It is extremely doubtful that scientific data that can be used to support this assumption. It is clear that a plant dominated by E. cloacae, for example, will have a very different ratio to one that is dominated by E. sakazakii.
- Enterobacteriaceae can be used to predict E. sakazakii and that reductions in the levels of Enterobacteriaceae in powdered infant formula will lead to lower levels of E. sakazakii. This is not necessarily so.

Levels of E. sakazakii should be controlled to minimise the risk to the infants at greatest risk. We are concerned, however, that the proposed E. sakazakii microbiological criteria may not have sufficient scientific justification. Our reasons for this view are:

We agree with the recent IFT report (Managing Food Safety: Use of performance Standards and Other Criteria in Food Inspection Systems) that reacting too quickly by setting a scientifically invalid performance standard would be scientifically questionable and could create a false sense of lowered risk in the minds of care givers of infants at greatest risk. This also applies to the setting of microbiological criteria.

There seems as yet no scientific agreement on the acceptable level of E. sakazakii in infant formula. Any microbiological criteria should be based on knowledge of infective dose.

The FAO/WHO risk assessment indicates that minimising E. sakazakii levels in the infant formula has significantly less effect on risk reduction than does the handling of the infant formula after reconstitution. Therefore, establishing E. sakazakii microbiological criteria at very low levels may not be as effective as improving knowledge of reconstitution procedures.

International surveys of infant formulae show that the organism is frequently present at low levels. However occurrences of illness are rare.

SWITZERLAND

We propose the removal of the square brackets in the Table on microbiological criteria

UNITED STATES OF AMERICA

The U.S. Delegation supports the use of a criterion for *Enterobacteriaceae* as a replacement for coliform, fecal coliform and *E. coli*. However, we are uncertain as to the adequacy of the data to support the 2-class plan proposed. We feel that further discussion and debate and perhaps additional data is needed before deciding on a criterion for *Enterobacteriaceae.*

IDF

Regarding the specification for *Enterobacter sakazakii:*

Microbiological specifications can be used only for verification of the effective functioning of the entire combination of control measures applied and cannot replace target expressions related to appropriate level of protection. Therefore, and instead of establishing a MC, we highly recommend the establishment of a FSO for *E. sakazakii* for reconstituted products intended for the vulnerable group of infants (i.e. below 6 months of age). This will enable the design of appropriate measures and targets upstream the production and distribution chain. In this case, assurance of compliance to required outcome through microbiological testing for this organism is highly ineffective.

We particularly note that:

- International surveys of infant formulae show that the organism is frequently present at low levels. Even so, occurrences of illness are rare.
- The FAO/WHO workshop indicated that minimising *E. sakazakii* levels in the infant formula has significantly less effect on risk reduction than does the handling of the infant formula after reconstitution. Therefore, driving *E. sakazakii* limits to very low levels in dried end products does not necessarily achieve the risk reduction that is desired.
- Reacting too quickly by setting a scientifically invalid performance standard could create a false sense of lowered risk in the minds of care givers of infants at greatest risk. This also applies to the setting of microbiological criteria.

We are convinced that the best way to manage the risk associated with *E. sakazakii* (and *Salmonella*) in infant formula would be to establish food safety objectives for the different groups of infants affected, and to develop guidance on the establishment of appropriate POs. As this is not easy to decide without thorough reflection, IDF suggests a working group could be established by CCFH with a remit similar to the one given to the "Lm control group" with the aim at developing an Annex similar to the one currently attached to the Listeria document.

Regarding the specification for Enterobacteriaceae: a) The purpose of establishing MC for *Enterobacteriaceae* would be to providing a measurement for

(i) verification of effective hygienic control, i.e. as an indicator for the degree of post-contamination from the packaging environment

(ii) assessing an end product (for possible release) in case monitoring shows that CCP(s) are not in control (see V.2.3, last para.)

However, with regard to (i) above, the probability of detecting post-contaminated *Enterobacteriaceae* in the product is very low (low levels, low frequency), wherefore random sampling and analysis will not be effective compared to other means of verification (see V.2.3, 3rd para). Finding any recontaminated products through such testing will be coincidental, provided adequate hygienic control in packaging environments. *Enterobacteriaceae* is a useful parameter for monitoring the effectiveness of control measures applied to control processing/packaging environment and equipment surfaces, as discussed in Annex II.

Testing of end product makes only sense when the likelihood of post-contamination is high and that post-contaminated lots are frequently occurring and equally distributed. This may very well be the case if monitoring shows that CCP(s) are not in control or if hygienic control of the packaging environment is inadequate. Consequently, the MC for *Enterobacteriacea* should only apply for such purposes (see (ii) above).

Problems arise when more is read into *Enterobacteriaceae* counts than can be scientifically supported. An *Enterobacteriaceae* microbiological criteria based on the desired *E. sakazakii* level in infant powder and using a general and notional *Enterobacteriaceae* / *E. sakazakii* ratio is questionable.

For instance, the footnote "**" assumes a direct relationship between *Enterobacteriaceae* levels and *E. sakazakii* that has not been established. The document further implies that *Enterobacteriaceae* can be used to predict *E. sakazakii* and that reductions in the levels of *Enterobacteriaceae* in powdered infant formula will lead to lower levels of *E. sakazakii*. The application of this assumption on a generic level is not supported by any data. The proportion may very between manufacturing plants.

The document implies that a safe *Enterobacteriaceae* / *E. sakazakii* ratio can be determined. It should be emphasized that the ratio vary between manufacturing plants. It is clear that a plant dominated by *E. cloacae*, for example, will have a very different ratio to one that is dominated by *E. sakazakii*.

ISDI

ISDI supports this criterion (Mesophilic Aerobic Bacteria) which is the existing one for dried infant formula (CAC/RCP 21-1979). Delete the criteria for *E.sakazakii.*

Rationale for supporting the criterion for Mesophilic Aerobic Bacteria: Indeed, infant formulae are manufactured from natural raw materials, with the majority being based on animal milk that has a microflora derived from the animal itself, and the environment during milking. This microflora is comprised mainly of benign bacteria that are destroyed during heat processes that are applied during the processing of the milk and during the manufacturing process of the formulae. Non-pathogenic aerobic spore forming bacteria, if present, survive this process. These together with a low level of non-pathogenic environmental bacteria make up the mesophilic aerobic bacteria in infant formula at the level of the current standard.

The microbiological criteria proposed in [ ] for Enterobacteriacea and *E.sakazakii* have been suggested by ICMSF, based on the risk assessment performed by the FAO/WHO in February 2004. This risk assessment was made with the data available at that time; these data were limited and may have led to a too stringent criterion for Enterobacteriacea. ISDI understands that new data have been submitted following the second FAO/WHO call for data. This will certainly allow to further refine the risk assessment and it is therefore proposed that the microbiological criteria are revisited on the basis of the evolving risk assessment.

ISDI supports the views from EFSA that "*No matter which of those PO´s is selected, the assurance of compliance by microbiological testing will be impossible and ineffective. (…) In some situations, in order*

to ensure that a Performance Objective is reached, microbiological testing might be an option. In the case of E. sakazakii and Salmonella in infant formula the introduction of a microbiological criterion for these specific pathogen organisms is not recommended. Enterobacteriaceae, which are more often present than E. sakazakii and Salmonella, could be used as an indicator for risk and a criterion established for the presence of Enterobacteriaceae in powdered infant formula."

The proposed Codex sampling plan is designed to detect 1 Enterobacteriaceae at a level of 1 in 25g (95% probability of detection). **The majority of ISDI members considers this as too stringent and supports a sampling plan, either a 2-class or 3-class plan, allowing to detect Enterobacteriaceae at a level of 1 in 10g.**

Comparison of Proposed 2-Class plan for Enterobacteriaceae to 3-Clss Plan

IDF

The information concerns the probability of rejecting a lot on the correct basis, considering a selected concentration (assumed as evenly distributed). For the further development of the Code, it would be very helpful to address the statistical probability of meeting the different types of criteria in relation to expected concentration, as such information would provide guidance as to whether the criteria would be useful as a means of verification; For instance, if probability of exceeding the criterion is very low, e.g. 10^{-4} or 10^{-5}, then testing against the criterion would not be useful, as (practically speaking) all test results will show compliance.

Annex II

VERIFICATION PROCEDURES USING ENVIRONMENTAL TESTING FOR POWDERED INFANT FORMULA

NEW ZEALAND

We note that this annex contains information relating to product as well as environmental monitoring. If this is to remain we suggest that consideration be given to amending the Annex title to better reflect the content.

FOURTH PARAGRAPH

IDF

We agree that *Enterobacteriaceae* is a feasible indicator for environmental recontamination. However, we have sincere doubts that microbiological testing of these organisms in end products is effective for verification of environmental control, due to the sporadic nature of contamination (if it occurs) and the low levels in question. These indicators can most effectively be used to verify cleanliness of the packaging environment.